

WHAT IS CLAIMED IS:

5 1. A pharmaceutical suspension formulation
suitable for aerosol administration, consisting
essentially of a therapeutically effective amount of a
drug and a propellant selected from the group
consisting of HFC 134a, HFC 227, and a mixture thereof,
10 the formulation being further characterized in that it
exhibits substantially no growth in particle size or
change in crystal morphology of the drug over a
prolonged period, is substantially and readily
redispersible, and upon redispersion does not
15 flocculate so quickly as to prevent reproducible dosing
of the drug.

 2. A formulation according to Claim 1,
wherein the propellant is a mixture of HFC 134a and HFC
20 227.

 3. A formulation according to Claim 1,
wherein the propellant is HFC 227.

25 4. A formulation according to Claim 1,
wherein the propellant is HFC 134a.

 5. A formulation according to Claim 1,
wherein the drug concentration is less than about 0.1
30 percent.

 6. A formulation according to Claim 1,
wherein the drug concentration is greater than about
0.1 percent and less than about 0.5 percent.
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 7. A formulation according to Claim 1,
wherein the drug concentration is greater than about
0.5 percent.

8. A formulation according to Claim 1,
wherein the drug has a potency such that a
concentration of less than about 0.1 percent is
5 therapeutically effective.

9. A formulation according to Claim 1,
wherein the drug is selected from the group consisting
of formoterol, salmeterol, and a pharmaceutically
10 acceptable salt thereof.

10. A formulation according to Claim 1,
wherein the drug is formoterol fumarate.

15 11. A formulation according to Claim 10,
wherein the formoterol fumarate is present in an amount
of about 0.01 percent to about 0.10 percent.

12. A formulation according to Claim 11
20 wherein the formoterol fumarate is present in an amount
of about 0.02 percent.

13. A formulation according to Claim 11,
wherein the propellant is HFC 134a.
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14. A formulation according to Claim 11,
wherein the propellant is HFC 227.

15. A formulation according to Claim 12,
30 wherein the propellant is HFC 134a.

16. A formulation according to Claim 1,
wherein the drug is selected from the group consisting
of albuterol, beclomethasone dipropionate, cromolyn,
35 pirbuterol, and a pharmaceutically acceptable salt or
solvate thereof.

17. A formulation according to Claim 1, wherein the drug is selected from the group consisting of albuterol sulfate, disodium cromoglycate, and pirbuterol acetate.

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18. A formulation according to Claim 5, wherein the drug is selected from the group consisting of beclomethasone dipropionate, albuterol, formoterol, and pirbuterol, and a pharmaceutically acceptable salt or solvate thereof.

19. A formulation according to Claim 4, wherein the drug is selected from the group consisting of beclomethasone dipropionate, albuterol, formoterol, and pirbuterol, and a pharmaceutically acceptable salt or solvate thereof, and wherein the drug is present in an amount of greater than about 1.6 percent.

20. A formulation according to Claim 3, wherein the drug is disodium cromoglycate, and the drug is present in an amount of less than about 0.1 percent.

21. A formulation according to Claim 3, wherein the drug is disodium cromoglycate, and the drug is present in an amount greater than about 1.4 percent.

22. A formulation according to Claim 2, wherein the drug is formoterol fumarate.

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23. A formulation according to Claim 22, wherein the mixture contains substantially equal amounts of HFC 134a and HFC 227.

24. A formulation according to Claim 2, wherein the drug is beclomethasone dipropionate or a pharmaceutically acceptable solvate thereof.

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25. A formulation according to Claim 24, wherein the mixture contains substantially equal amounts of HFC 134a and HFC 227.

5 26. A formulation according to Claim 5, wherein the drug is salmeterol.

 27. An aerosol canister containing a formulation according to Claim 1 in an amount
10 sufficient to provide a plurality of therapeutically effective doses of the drug.

 28. A metered dose aerosol canister containing a formulation according to Claim 1 in an
15 amount sufficient to provide a plurality of therapeutically effective doses of the drug.

 29. A method of preparing a formulation according to Claim 1, comprising the steps of: (i)
20 combining an amount of the drug sufficient to provide a plurality of therapeutically effective doses and a propellant selected from the group consisting of HFC 134a, HFC 227, and a mixture thereof in an amount sufficient to propel from an aerosol canister a
25 plurality of therapeutically effective doses of the drug; and (ii) dispersing the drug in the propellant.

 30. A method of treating a mammal having a condition capable of treatment by inhalation,
30 comprising the step of administering by inhalation a formulation according to Claim 1 to the mammal.

 31. A suspension aerosol formulation comprising a therapeutically effective amount of
35 micronized drug selected from the group consisting of pirbuterol acetate and pirbuterol hydrochloride, and a propellant comprising HFC 227 the formulation being

further characterized in that it is substantially free of perfluorinated surfactant.

32. A formulation according to Claim 31,
5 wherein the drug is pirbuterol acetate.

33. A formulation according to Claim 32,
containing about 0.4 to about 1.0 percent by weight
pirbuterol acetate.

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34. A formulation according to Claim 32,
containing about 0.45 to about 0.9 percent by weight
pirbuterol acetate.

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35. A formulation according to Claim 32,
wherein HFC 227 is substantially the only propellant.

36. A formulation according to Claim 35,
substantially free of ethanol.

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37. A formulation according to Claim 32,
further comprising about 0.1 to about 12 percent by
weight ethanol.

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38. A formulation according to Claim 32,
further comprising about 2 to about 8 percent by weight
ethanol.

39. A formulation according to Claim 32,
30 further comprising about 5 to about 12 percent by
weight ethanol.

40. A formulation according to Claim 37,
further comprising about 0.01 to about 0.5 percent by
35 weight oleic acid.

41. A formulation according to Claim 32, consisting essentially of HFC 227 and a therapeutically effective amount of pirbuterol acetate.

5 42. A formulation according to Claim 41, wherein the pirbuterol acetate is present in an amount of about 0.4 to about 1.0 percent by weight.

10 43. A formulation according to Claim 32, consisting essentially of a therapeutically effective amount of pirbuterol acetate, about 5 to about 12 percent by weight ethanol, and HFC 227.

15 44. A method for inducing bronchodilation in a mammal, comprising the step of administering by inhalation to the lung of the mammal an amount of a formulation according to Claim 32 effective to induce bronchodilation.

20 45. A method of preparing a formulation according to Claim 32, comprising the steps of:
 (i) combining the micronized pirbuterol acetate with the propellant; and
 (ii) dispersing the pirbuterol acetate in the
25 propellant.

46. A formulation according to Claim 32 in an aerosol vial equipped with a metered dose valve.

30 47. A suspension aerosol formulation comprising a therapeutically effective amount of micronized albuterol sulfate and HFC 227 as substantially the only propellant.

35 48. A formulation according to Claim 47 wherein the micronized albuterol sulfate is present in an amount of about 0.2 to about 0.5 percent by weight.

49. A formulation according to Claim 47, wherein said formulation is substantially free of perfluorinated surfactant.

5 50. A formulation according to Claim 47 further comprising from about 0.1 to about 20 percent by weight of ethanol.

10 51. A formulation according to Claim 50, wherein said ethanol is present in an amount of about 5 to about 15 percent by weight.

15 52. A formulation according to Claim 51 further comprising from about 0.01 to about 0.5 percent by weight of a surfactant selected from the group consisting of oleic acid and sorbitan trioleate.

20 53. A formulation according to Claim 52, wherein said surfactant is oleic acid.

54. A formulation according to Claim 52, wherein said surfactant is sorbitan trioleate.

25 55. A formulation according to Claim 47 consisting essentially of about 0.2 to about 0.5 percent by weight of micronized albuterol sulfate and HFC 227.

30 56. A formulation according to Claim 47 consisting essentially of about 0.35 to about 0.42 percent by weight of micronized albuterol sulfate and HFC 227.

35 57. A formulation according to Claim 51 consisting essentially of about 0.2 to about 0.5 percent by weight of micronized albuterol sulfate, about 5 to about 15 percent by weight of ethanol, and HFC 227.

58. A method for inducing bronchodilation in a mammal comprising the step of administering by inhalation to the lung of the mammal an amount of a formulation according to Claim 47 effective to induce
5 bronchodilation.

59. A method of preparing a formulation according to Claim 47, comprising the steps of:

- 10 (i) combining the micronized albuterol sulfate with the propellant; and
(ii) dispersing the albuterol sulfate in the propellant.

60. A formulation according to Claim 47 in
15 an aerosol vial equipped with a metered dose valve.